UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *County of Trumbull, Ohio v. CVS Health Corp., et al.,* Case No. 1:18-op-45079 *County of Lake, Ohio v. CVS Health Corp., et al.,* Case No. 1:18-op-45032	MDL No. 2804 Case No. 1:17-md-2804 Judge Dan Aaron Polster

RITE AID DEFENDANTS' TRIAL BRIEF

Defendants Rite Aid of Ohio, Inc. ("RA Ohio"), Rite Aid of Maryland, Inc. dba Rite Aid Mid-Atlantic Customer Support Center ("RA Maryland"), Rite Aid Hdqtrs. Corp. ("RA Hdqtrs."), and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center ("RA Liverpool") (collectively, "Rite Aid Defendants") submit this Trial Brief describing how they intend to defend the public nuisance claims of Plaintiffs Trumbull County and Lake County ("Plaintiffs" or "Counties"). The Rite Aid Defendants reserve the right to supplement or modify their defenses described below based on the evidence at trial, rulings by the Court, and the significant time and witness constraints on trial imposed by the Court. The Rite Aid Defendants preserve all prior objections, including but not limited to legal issues, and the right to make further evidentiary and other objections at trial.

Plaintiffs cannot meet their burden of proving that Rite Aid is liable for a public nuisance that allegedly exists today. No Rite Aid defendant has engaged in intentional and unreasonable conduct intending to cause a significant interference with a right to public health or engaged in any illegal conduct under federal or state law. To the contrary, the Rite Aid Defendants at all times acted to promote public health in compliance with applicable federal and state law through their reasonable and appropriate policies and procedures and corporate initiatives, and they at all times reasonably believed their conduct was lawful based on (among many other reasons) DEA inspections of their distribution centers and Ohio Board of Pharmacy inspections of Rite Aid pharmacies (none of which found material deficiencies in policies or procedures), and regular renewals of their regulatory licenses. Rite Aid pharmacists assisted local law enforcement in their diversion investigations, and Plaintiffs' local law enforcement *never* alleged illegal dispensing conduct at any Rite Aid pharmacies. The Rite Aid Defendants at all times engaged in lawful conduct that cannot form the basis of a public nuisance. In the highly-regulated environment of

the distribution and dispensing of prescription drugs, because all Rite Aid Defendants fully complied with the law, they cannot be held liable for public nuisance under another theory.

Far from interfering with public health, the Rite Aid Defendants' distribution and dispensing of opioid medications supported the public health by ensuring that patients could obtain and utilize lawful opioid medications prescribed by their physicians for the legitimate purpose of treating acute and chronic pain, including for cancer, palliative, and end-of-life care. One of the central purposes of the Controlled Substances Act is to ensure a continuous and uninterrupted supply of controlled substances for legitimate medical needs. 21 U.S.C. § 801(1). The Drug Enforcement Administration ("DEA") in fact determined there was an increasing medical need for opioid medications, which is why it consistently increased the Aggregate Production Quota for hydrocodone and oxycodone almost every year through 2013. It is Plaintiffs' theory, not Rite Aid's conduct, that would improperly interfere with public health by applying rigid, arbitrarily applied, litigation-driven "red flags" to interfere with patients' right to use lawful medications prescribed by their physicians based on their unique conditions and circumstances.

Plaintiffs' Dispensing Theory Is Meritless

DEA regulations require that a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR § 1306.04(a). "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but *a corresponding responsibility rests with the pharmacist* who fills the prescription." 21 CFR § 1306.04(a) (emphasis added).

Plaintiffs can prove a violation of corresponding responsibility only if they can establish scienter—that Rite Aid pharmacists knowingly dispensed opioid medications pursuant to a

prescription without a legitimate medical purpose or a prescription not issued in the usual course of practice. *Id*. at § 1306.04(a) ("An order purporting to be a prescription issued not in the usual course of professional treatment … is not a prescription with the meaning and intent … of the Act and the person *knowingly filling* such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." (emphasis added)). This is not a negligence case, and Plaintiffs cannot use "aggregate data" prove scienter for the many different Rite Aid pharmacists who filled the prescriptions that Plaintiffs now claim should not have been filled.

Rite Aid's pharmacists were trained and licensed in the state of Ohio and knew how to evaluate potential "red flags" of diversion even before they received their licenses. RA Ohio had appropriate policies and procedures in place pertaining to controlled substances and corresponding responsibility. Rite Aid's pharmacists had access to patient profiles, drug utilization review software, alerts while evaluating opioid prescriptions, and access to OARRS. And the pharmacists knew many of their patients, including their conditions and medication histories, and were able to use that pre-existing knowledge in exercising their corresponding responsibility on a prescription-by-prescription basis. Rite Aid also provided its pharmacists with reminders and tools for the exercise of professional judgment in dispensing opioid medicines, including training and, in 2013, a six-step process that formalized the pre-existing procedure for reviewing controlled substance prescriptions. In 2015, Rite Aid automated that process so that pharmacists had to confirm in the Rite Aid system that they completed a step before moving onto the next step. Its Pharmacy District Managers and Regional Healthcare Leaders regularly visited the stores to monitor pharmacy operations, including compliance with corresponding responsibility, and exercised appropriate oversight, as did Rite Aid's Government Affairs and asset protection/loss prevention groups. Rite

Aid conducted internal audits and store self-audits, including to ensure that appropriate security was installed in stores. No Rite Aid pharmacy in either County was a pill mill or ever had its license suspended or revoked by the DEA or the Ohio Board of Pharmacy. Both loss prevention/asset protection representatives and pharmacists cooperated with local law enforcement by reporting potential diversion and cooperating in law enforcement investigations. Indeed, local law enforcement investigations of doctor-shoppers and illegitimate prescribers often began with tips from pharmacists at Rite Aid and other chain pharmacies.

Plaintiffs' reliance on algorithms and raw dispensing data to identify prescriptions with purported red flags is unreliable and does not account for the individual exercise of professional judgment by individual Rite Aid pharmacists based on the information known to those pharmacists each time they were presented with an opioid prescription. Plaintiffs' pharmacy expert (Carmen Catizone) simply *assumed* that the pharmacists failed to clear what he considered to be "red flags"—he conceded that he did not review the information actually known to or considered by Rite Aid's pharmacists. Documentation of clearing "red flags" has never been required by any regulator or pharmacy practice, and there is no basis to assume that the absence of a note signifies a failure to clear a red flag when the appropriate due diligence depends on the facts and circumstances of a particular patient and prescription. Catizone also admitted during his deposition that a flagged prescription may have a legitimate medical purpose and/or may not have been diverted or may not even be a "red flag" at all. Nor did Plaintiffs' addiction expert (Anna Lembke), a medical doctor, review prescriptions to assess medical appropriateness; instead, she opined on pharmacy matters for which she has no education, training, or experience.

Plaintiffs' arguments require a revisionist interpretation (or outright disregard) of the medical standards in effect from the late 1990s through 2016, when the CDC eventually issued its

guidelines for treating pain with opioid medications. Prescribers (especially doctors) prescribed increasing amounts of opioids because the medical standard of care/prescribing habits for pain changed over time. Beginning in the late 1990s into the early 2010s, medical authorities such as the Joint Commission and Boards of Medicine determined that pain was undertreated and that doctors (in particular) should prescribe more opioid medications to treat pain. The logical consequence of the changing standard of care was more opioid prescriptions and thus larger quantities of opioid medicines distributed and dispensed.[1]

Using hindsight and more recent medical thinking about opioid medications, Plaintiffs now claim that many of those prescriptions lacked a legitimate medical purpose. But regardless whether doctors might make different treatment decisions today, doctors considered opioid medications to have a legitimate medical purpose throughout the relevant time period, and the DEA has determined at various times that the overwhelming majority of doctors (up to 99.9%) properly prescribed opioid medications. Those prescriptions in turn were filled by pharmacists who exercised professional medical judgment in the context of a specific patient and prescription. Given that both the prescriber and the pharmacist individually exercised professional judgment based on then-existing medical standards and the information known to them (which was not equivalent and varied by patient), Plaintiffs cannot show that RA Ohio's pharmacists violated their corresponding responsibility.

RA Ohio's fact and expert witnesses will testify that it had appropriate policies and procedures in place to properly dispense opioid medications and effective controls against

[1] Plaintiffs originally started the opioid litigation in 2017 by suing Purdue Pharmaceuticals and other manufacturers, blaming them for the opioid crisis and not the chain pharmacy defendants. According to Plaintiffs, Purdue's marketing and other efforts led to changes in medical practice that made opioid medications front-line treatment for acute and chronic pain. Those judicial admissions regarding the changing standard of care are binding on Plaintiffs.

diversion, as well as concerning the medical standard of care that caused increased prescribing of opioid medications over time and, in turn, lawful increased dispensing.

Plaintiffs' Distribution Theory Is Meritless

Plaintiffs also contend that the RA Perryman and RA Liverpool ("RA Distributors") violated the CSA by failing to maintain effective controls against diversion in their distribution of certain hydrocodone combination products ("HCP") to Rite Aid pharmacies in the Counties. In distributing HCPs to its pharmacies, the RA Distributors at all times complied with the CSA through implementation of appropriate policies and procedures, security procedures, and suspicious order monitoring.[2]

In particular, the RA Distributors knew their customers, which were Rite Aid owned and operated pharmacies that maintained appropriate policies, procedures, protocols, and training concerning dispensing of controlled substances, conducted internal audits, and maintained asset protection/loss prevention functions. The DEA and state regulators routinely renewed their registrations and licenses following inspections and audits, with the DEA even praising RA Maryland for maintaining an excellent suspicious order monitoring system. The RA Distributors complied with the security requirements and maintained effective controls. 21 CFR § 1301.71(b); 21 C.F.R. § 1301.74(b).

Because Rite Aid pharmacists filled lawful prescriptions with the HCPs distributed by RA Distributors, the orders for these medications placed by the Rite Aid pharmacies could not have been "suspicious," and there was nothing wrongful about RA Distributors filling the orders and distributing HCPs to the pharmacies.

[2] RA Hdqtrs. provided services to the Rite Aid distribution centers and retail pharmacies. It was not a registrant under the CSA or Ohio law and neither distributed nor dispensed controlled substances. Distribution by the Rite Aid Distributors ceased in September 2014 shortly before the DEA converted HCPs to Schedule II.

In addition, the RA Distributors had a reasonable and appropriate suspicious order monitoring ("SOM") system under 21 C.F.R. § 1301.74(b) as demonstrated by the following efforts:

- RA Ohio utilized an algorithm-based automated replenishment system ("ARS") that determined recommended orders based on a 13-week rolling average that took into account controlled substances on hand (whether distributed by the RA Distributors or McKesson) and those that had been dispensed. As a result, there were no orders of unusual size or outside a normal pattern.

- The RA Distributors also used a threshold system to limit the size of orders (with certain limited exceptions not applicable here) to 5,000 dosage units per NDC per order. In the event an order exceeded 5,000 dosage units (even if recommended by the ARS), distribution centers employees were trained to reduce the order to 5,000 units. Employees sought to contact a pharmacist at the store that placed the above-threshold order to inquire about the order and to advise that the order would be cut. The employees maintained logs of all such orders. This ensured there were no orders of unusual size or orders that deviated substantially from a normal pattern.

- The RA Distributors generally distributed only once per week to stores in the Counties, thereby ensuring no orders of unusual frequency.

- RA Hdqtrs. maintained a Government Affairs group that oversaw compliance with regulations and was knowledgeable as to both distribution and dispensing practices.

- RA Hdqtrs. also maintained a loss prevention/asset protection group that regularly and proactively evaluated key performance indicators relating to controlled substances as an anti-diversion and anti-loss measure. That group also investigated potential losses.

In addition to fact testimony, Rite Aid will present expert testimony from a former DEA manager and an economist (who is also a medical doctor) who evaluated those measures in the context of Rite Aid's pharmacy operations and the prevailing medical practices for prescribing opioid medications. Both experts confirmed that the RA Distributors maintained effective controls against diversion.

Plaintiffs Cannot Show Proximate Causation

Nor can Plaintiffs prove that the conduct of any Rite Aid entity proximately caused a significant interference with public health. RA Ohio operated five (5) brick-and-mortar

pharmacies in Lake County and ten (10) in Trumbull County, dispensing opioids to only a small percentage of Plaintiffs' residents. The Rite Aid Defendants reported all opioid medications dispensed by its pharmacists to the Ohio Automated Rx Reporting System ("OARRS") and also reported to the DEA through ARCOS (Automation of Reports and Consolidated Orders System) all opioid shipments from RA Perryman and RA Liverpool (which operated Rite Aid distribution centers) into the Counties. Federal and state regulators at all times had access to ARCOS and OARRS data to identify and stop potential sources of diversion in the Counties—yet they never identified any diversion occurring at any Rite Aid pharmacy in the Counties that was not first reported by RA Ohio.

Plaintiffs rely on undeniably tragic statistics concerning opioid overdoses and deaths and of social services related to opioid misuse and abuse. But Plaintiffs cannot connect those statistics to opioid medications knowingly dispensed by Rite Aid pharmacists pursuant to an illegitimate prescription or to any opioid medications distributed to a Rite Aid pharmacy after a "suspicious order" to a RA Distributor. Plaintiffs' inability to demonstrate that *wrongful* conduct by the Rite Aid Defendants *actually causes specific harm* of sufficient magnitude *today* that it significantly interferes with public health is a fundamental, irremediable failure of proof in Plaintiffs' claim.[3]

Moreover, Plaintiffs *never* sought to determine the underlying circumstances of opioid use, misuse, and abuse that could potentially attribute culpability to a specific actor: the original source

[3] The Rite Aid Defendants expect Plaintiffs to focus on statistics as to the quantity of opioid medications supplied to the Counties to argue a purported "oversupply" of opioid medicines and that misuse and abuse increased while supply increased, blaming Defendants because of the quantity of opioid medicines they dispensed. But the supply was determined by the DEA (Annual Production Quotas) and local doctors in and around the Counties (including from the Cleveland Clinic) who determined that those prescriptions were medically appropriate. Of course, Plaintiffs have no expert evidence as to what the appropriate supply, in their view, currently is or should have been in either County. Rather than actual causation evidence, Plaintiffs likely will seek to inflame the jury through irrelevant and unfairly prejudicial evidence involving an unreasonably and unfairly long time period—2006 to 2019 or 2020—despite that this Court has imposed severe restrictions on the amount of time and number of witnesses available for the defense. As an illustration, Plaintiffs seek to use a 2009 DEA settlement against the Rite Aid Defendants that involves conduct from 2006 and earlier, none of which involved stores in Ohio.

of an affected individual's opioid medications; whether a particular individual was legitimately prescribed and dispensed an opioid medication; whether an individual began misusing or abusing prescription opioid medications without receiving a prescription or commenced misuse or abuse after the prescription ended; the duration of use and whether the individual followed the prescriber's directions; whether an individual was actually diagnosed with an addiction and, if so, the circumstances leading to the addiction; whether an individual experienced polysubstance abuse or had a preexisting substance abuse history unrelated to opioid medications. Plaintiffs' "gateway" theory suffers from the same failures, effectively *assuming* that the Rite Aid Defendants are responsible for heroin use without evidence of a single heroin user in either county whose use began because a licensed Rite Aid pharmacist *knowingly* filled an illegitimate prescription.

Evidence will show that many individuals misuse or abuse prescription opioids (or use heroin) without ever being prescribed opioid medications. The original source of the prescription opioids is often unknown. And individuals use heroin (and fentanyl, frequently unknowingly) for myriad reasons, including low price and easy availability. Harm can occur from lawful use of opioid medications and illicit use. But Plaintiffs' evidence of causation and harm does not distinguish between lawful and illicit use.

Finally, the overwhelming majority of diversion occurs after a pharmacist properly fills a prescription for an opioid medication. Patients may misuse opioid medications contrary to healthcare practitioners' directions for use. They may give or sell unused medication to others who in turn misuse or abuse the medication. Or, friends, family or invitees may remove medication from medicine cabinets or other areas of a residence because the patient did not properly secure the medication. Plaintiffs' theories ignore and fail to account for this primary cause of diversion.

No pharmacist or pharmacy can prevent post-dispensing diversion of a properly dispensed medication. But none of that matters under Plaintiffs' undifferentiated causation theory.

Conclusion

Rite Aid anticipates filing a motion for judgment as a matter of law pursuant to Rule 50 of the Federal Rules of Civil Procedure. Based on applicable law and undisputed facts, the Court should enter judgment for the Rite Aid Defendants at the close of Plaintiffs' case-in-chief.

Dated: August 19, 2021

Respectfully submitted,

/s/ Kelly A. Moore

Kelly A. Moore
kelly.moore@morganlewis.com
Morgan, Lewis & Bockius LLP
101 Park Avenue
New York, NY 10178-0060
T: 212-309-6612
F: 212-309-6001

John P. Lavelle, Jr.
Elisa P. McEnroe
elisa.mcenroe@morganlewis.com
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103-2921
T: 215-963-5917
F: 215-963-5001

John K. Gisleson, Esquire
john.gisleson@morganlewis.com
Morgan, Lewis & Bockius LLP
One Oxford Centre
Thirty-Second Floor
Pittsburgh, PA 15219-6401
(412) 560-3300 (telephone)
(412) 560-7001 (facsimile)

Counsel for Rite Aid of Ohio, Inc., Rite Aid of Maryland, Inc. d/b/a Mid-Atlantic Customer Support Center, Rite Aid Hdqtrs. Corp., and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center

CERTIFICATE OF SERVICE

I certify that on August 19, 2021, the foregoing was electronically filed using the Court's CM/ECF system, and all counsel of record were served by operation of that system.

/s/ Kelly A. Moore
Kelly A. Moore